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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,168	09/25/2003	Gil M. Vardi	1001.2278101	2222

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

MAIL DATE	DELIVERY MODE
09/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,168	VARDI ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 1993*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8,28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08042009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/04/09 has been entered.

Priority

2. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Claim Rejections - 35 USC § 112

3. Claims 1, 4, 5, and 8 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation “the branch guidewire enclosure is bonded to the first tubular member only at the branch exit port.” This limitation does not find proper support in the specification for the following reasons.

First, because the port is an opening in the tube, it is no possible for a bond to occur at the port. Secondly, if one was to broadly interpret the claim such that “at” is interpreted as near or surrounding, the claim limitation would not have support because the branch guidewire location is not bonded to the tubular member "only” near the branch exit port, but also near the main exit port. Thirdly the specification ([Para 0031]) provides support for, “distal shaft 26 can be attached to inflation tube 22 *only* in the *region* of ***bond portion*** 24.” (emphasis added). It does not provide support for “only at the branch exit port”.

Claim Rejections - 35 USC § 103

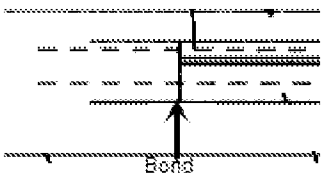
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 6,099,497) as evidenced by Ischinger (US6,682,556).

6. Adams discloses a catheter comprising: a proximal tube extending from a proximal end to a distal end; a first distal tube (134) having an opening (C10:L18-24), the first distal tube being configured to receive a first guidewire (58); a second distal tube (136) having an opening (C10:L18-24), the second distal tube being configured to receive a second guidewire (60); and a bond having a proximal end (left side of junction shown below) and a distal end (right side of junction shown below), the proximal end of

the bond coupled to the distal end of the proximal tube, the distal end of the bond coupled to the first distal tube adjacent to the opening (note that C10:L18-24 states that the guidewire lumens extend proximally of the proximal end of the balloon and so would be considered adjacent or near the bond) such that the opening of the first distal tube remains open to define a first guidewire exit port, and the distal end of the bond coupled to the second distal tube adjacent to the opening (note that C10:L18-24 states that the guidewire lumens extend proximally of the proximal end of the balloon and so would be considered adjacent or near the bond) such that the opening of the second distal tube remains open to define a second guidewire exit port detached from the first distal.



Regarding claim 31: a balloon with inflation lumen (124) and a stent (Fig. 7a, 64) having a lumen and a side opening (68). Regarding claim 32: the second distal tube is detached form the first distal tube outside the bond (see Fig. 14D, 17 and 18). Regarding claim 33: the second distal tube does not include a balloon (see Fig. 14D, 18).

7. Adams does not disclose that the openings (guidewire ports) are proximal open ends of the first and second distal tubes since Adams discloses only that the openings are located proximally of the proximal end of the balloon. Adams does not disclose the length of the guidewires. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the size of the catheter and

therefore the location of the exit ports and length of the guidewire depending on the size and location of the lumen in which it would be used. For instance catheter used on an infant would be significantly smaller than that used on a large adult. Additionally, a catheter that is being delivered to the aorta will be larger than one that is being delivered to the brain. Such a modification would have involved a mere change in the size of a component, and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Since it would a matter of obvious design choice in determining the location of the exit ports, it would be well within the skill of the ordinary artisan to choose the location of the exit ports for the guidewires at the proximal end of the first and second distal tubes (for example as evidenced by Fig. 1b, Ischinger (US 6,682,556). Regarding claim 29, the first and second guidewires would be configured to exit the catheter at the proximal open ends of the first and second distal tubes.

8. Claims 1, 4, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (US 6,099,497) in view of Keith (US 6,273,879).

9. Adams discloses a catheter system (Fig. 14A- 4D, 17, 18) for positioning a stent at a vessel bifurcation, the catheter system comprising: a catheter including a proximal end and a distal end, the catheter comprising: a first tubular member (for example 122) including a proximal end and a distal end, the first tubular member defining an inflation (132) lumen of the catheter and extending distally from the proximal end of the catheter; a second tubular (134) member defining channel having a main guidewire lumen

extending proximally from a distal end of the second tubular member to a proximal end of the second tubular member, wherein the distal end of the second tubular member is a distal end of the catheter (see Fig. 14a) and the proximal end of the second tubular member defines of a main guidewire exit port (C10:L18-24), wherein the main guidewire lumen is configured to receive a main vessel guidewire (58) therethrough, wherein the second tubular member is at least partially disposed within the inflation lumen of the first tubular member (see Fig. 14a and C9:L61-66); a balloon (124) including a proximal waist (126) coupled to the first tubular member (C10:L51-54) and a distal waist (128) coupled (indirectly) to the second tubular member adjacent to the distal end of the second tubular member; a branch guidewire enclosure (136) positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen configured to receive a branch vessel guidewire (60) therethrough, a proximal end of the branch guidewire enclosure defining a branch guidewire exit port (C10:L18-24); and a stent (for example Fig. 7a, 64) having a lumen and a side opening (68) in a wall thereof, the stent positioned about at least a portion of the balloon, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen of the stent (C11:L24-30) and exits at the side opening; wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter (c10:L18-24). The catheter further comprises a bond portion coupling the first tubular member, the second tubular member and the branch guidewire enclosure (since the term “portion” is broad and user selectable to include all three elements)

10. With respect the limitation of claim 1, “wherein the branch guidewire enclosure is bonded to the first tubular member *only at* the branch exit port”, Adams does not explicitly disclose the location of the exit ports of the second tubular member and the branch guidewire enclosure. However, it is presumed that this recitation is not meant to be interpreted as the bond only occurring at the location of the port since a port is an opening and as such could not be bonded to anything. Thus the limitation is interpreted as the guidewire enclosure bonded to the first tubular member only *near or in the area surrounding* the branch exit port. For example the specification (Para [0031]) states, “distal shaft 26 can be attached to inflation tube 22 *only in the region of bond portion* 24", where "bond portion” can be broadly interpreted. That being said, Adams discloses the branch guidewire enclosure bonded to the first tubular member (as in Fig. 14d, 17 and 18). Adams also discloses the guidewire ports being located proximal of the balloon. Therefore the region of the bond portion is chosen to include the region where the tubes are bonded and the region where the ports are located.

11. Adams discloses that the proximal waist of the balloon is coupled to the first tubular member does not disclose that the balloon a balloon (124) including a proximal waist coupled to the first tubular member (C10:L51-54) but does not disclose that the proximal waist is coupled to the first tubular member *adjacent to the distal end of the first tubular member*. Adams does disclose that one preferred embodiment has the inflation lumen and the guidewire lumen coaxially disposed (C9:L60-64) but does not show how the balloon would be attached. However Keith discloses a common structure for quick exchange catheters where the first tubular member (for example 82) defining

the inflation lumen (for example 104) is coaxial with the second tubular member (for example 80) defining the guidewire lumen (for example 52). The first tubular member extends only to the proximal end of the balloon such that the proximal end of the balloon is coupled to the distal end of the first tubular member and the second tubular member extends through the balloon such that the distal end of the balloon is coupled to the distal end of the second tubular member. It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute the structure of Keith for the structure for the structure of Adams since they are know equivalent structures in the art. Substitution of one known element for the other would have yielded predictable results.

12. Regarding claims 5 and 8, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the location of the exit ports for the guidewires depending on the use of the device. For example, the location of the ports will vary depending on the size of the catheter and size of patient it is used in as well as the location in the body where the device is being delivered.

Response to Arguments

13. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
9/22/09